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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,584	Applicant(s) DEL NIDO ET AL.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 04 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because they are of poor quality: the numbers and reference characters are not plain and legible (37 CFR 1.84(p)) and the lines, numbers and letters are not uniformly thick and well defined, clean and durable (37 CFR 1.84(l)). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-5, 7-10, 22, 23, 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanden Hock (US Patent Application 2003/0004396; referred to hereafter as Hock'396).

Claim 1: Hock'396 discloses a device (Figure 6, 7) for deploying a material (10) that contains a housing (39) and a placement means (36a, 36b) having a retracted

condition within said housing (Figure 7) and an extended condition extended from the housing (Figure 6).

Claim 2: The housing includes an insertion end (proximal end) and an opposite end (distal end).

Claim 3: The housing includes a lumen connected the insertion end and opposite end (this is clearly shown in Figures 6 and 7 but the lumen is not labeled).

Claim 4: The placement means is disposed in the insertion end of the housing and through the lumen (Figures 6, 7).

Claim 5: The placement means includes a controlling means (32) for controlling movement of the device.

Claim 7: The placement means includes holding means (36a, 36b, 34) for holding the material on the placement means (paragraph [0082]).

Claim 8, 9: The holding means include curvate, radially outwardly extending arms that are formed of an umbrella shaped wire (Figure 6)

Claim 10: The holding means further includes spires (34) attached to the ends of the holding means to hold the material in place (paragraph [0082])

Claim 22: The device is capable of fitting within a trocar.

Claim 23, 27, 28: Hock'396 discloses a method of deploying a material (10) into a patient by actuating the placement means (36a, 36b) to an extended position and affixing a material to the placement device (paragraph [0082], [0087]); retracting the placement device into the housing with the material in the collapsed condition (paragraph [0087]); inserting the deploying device into the body of a patient (paragraph

[0087]); Extending the placement device into the extended condition in the body (paragraph [0088]) and placing the material at a predetermined site in the uncollapsed configuration (Figure 8).

Claim 25: Hock'496 discloses that the material is affixed to the placement device by threading a wire through the material (paragraph [0082]).

Claim 26: The wire of Hock'496 is removed after placement of the material (paragraph [0089]).

Claims 1-7, 11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakao et al. (US Patent 5,759,187).

Claim 1: Nakao'187 discloses a deployment device (Figure 32) for deploying a material (820) that contains a housing (812) and a placement means (814, 818) having a retracted position (described at column 18, line 66 to column 19, line 15) and an expanded position extending from the housing (shown in Figure 32).

Claim 2: The housing includes an insertion end (proximal end) and an opposite end (distal end).

Claim 3: The housing contains a lumen (see Figure 32).

Claim 4: The placement means is inserted into the insertion end and extends through the lumen (Figure 32).

Claim 5, 6: The placement means contains finger loops (816).

Claim 7: The placement means contains holding means for holding the material on the placement means (the material is held on the placement means, therefore there are holding means; Figure 32).

Claim 11, 20: The placement means contains a self-expanding ring (818) (column 19, lines 4-8). It is a shape memory alloy since it is an alloy that exhibits shape memory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao'187.

Claim 12, 13, 14, 16, 18: Nakao'187 discloses in a different embodiment in Figure 43 that contains a placement means having a ring (926) for carrying a material (928). The material in this embodiment is held on the ring with sutures/wires (930, 932) (column 24, lines 28-48). It would be obvious to apply the attachment mechanism of Figure 43 to the embodiment of Figure 32 since Nakao'187 states that it would be obvious to combine different embodiments without departing from the spirit of the invention (column 26, lines 48-57).

Further regarding Claim 12, the ring in Figure 43 contains a coiled loop (930, 932)

Claim 15, 19: Nakao'187 does not disclose the particular material that sutures/wires (930, 932) are made of, however, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the particular material disclosed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 17: Nakao'187 does not disclose the use of a needle to attach the material to the wire (930, 932), however, it would be obvious to do so, since it is old and well know to lace wire/suture through a mesh with the aid of a needle.

Claim 21: Nakao'187 does not disclose a particular material that the ring is made of, however, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a particular shape memory alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In *re Leshin*, 125 USPQ 416.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hock'496, as applied to claim 23, further in view of Wilk (US Patent 6,155,968).

Hock'496 teaches the limitations of Claim 24 except for the use of a trocar.

Wilk'968 teaches a similar method (column 1, lines 42-47) of delivering a compressive device to the heart. Wilk'968 teaches that the compressive device is delivered through a trocar (column 2, lines 61-67) in order to deliver the compressive device in a minimally invasive manner. It would have been obvious to one of ordinary skill in the art to modify the method of Hock'496, with the use of a trocar, as taught by Wilk'968, in order to deliver the compressive device during minimally invasive surgery.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 4:30 pm, and alternating Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner, Art Unit 3734